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David Keith James

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EXAMINER

LAVERT, NICOLE F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,378	Applicant(s) JAMES ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 40-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/30/07 & 6/13/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 40-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4 June 2008.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-6 & 22-26** are rejected under 35 U.S.C. 102(b) as being anticipated by Nagel et al. (US 4211237 A).

For **claim 1**, Nagel et al. discloses, apparatus for monitoring fetal behaviour comprising [fetomaternal electrocardiogram-see e.g., (col 3, line 42)]: an input for receiving ECG data (Figure 1, 201) from a set of electrodes attached to a maternal body [(col 9 & 10, lines 62-68 & 1-4) & (Figure 2, 301-303)]; a waveform pre-processor [microprocessor-see e.g., (Figure 3b, 33)] for identifying a succession of fetal ECG complex waveforms within the received data (col 3, lines 43-45); a waveform processor (Figure 3b, 33) for determining differences in the shapes of a succession of fetal ECG complex waveforms over time (col 3, lines 45-53); and an event logger [stored sample/ memory-see e.g., (col 3, lines 50) & (Figure 3b, 7)] determining from the determined differences (col 3, lines 45-53) a number of fetal movements during the period of

Art Unit: 3762

time (col 11, lines 50-61). Note that each disclosed QRS complexes of the fetal heart signals comprises of its own shape based on the variations of the QRS of the particular heart beat signals (col 3, ln 40-53).

In reference to **claim 2**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 further including a plurality of electrodes for positioning at different locations on the maternal abdomen [(col 9 & 10, lines 62-68 & 1-4) & (Figure 2, 301-303)].

In reference to **claim 3**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 2 in which the number of electrodes is two (Figure 2, 301-303).

In reference to **claim 4**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 in which the waveform pre-processor (Figure 3b, 33) includes a discriminator for discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform [Amplitude discriminator & f & m-sec e.g., (col 2, lines 35-42) & (Figure 2, 306)].

In reference to **claim 5**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 4, in which waveform pre-processor (Figure 3b, 33) includes means for subtracting the maternal ECG complexes from the received waveform (Figure 1, 204).

In reference to **claim 6**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 in which the waveform pre-processor (Figure 3b, 33) comprises means for identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

For **claim 22**, Nagel et al. discloses, a method for monitoring fetal behaviour comprising (col 3, lines 30-31): (i) obtaining fetal ECG data over a period of time (Figure 2, 301-303); (ii) identifying a succession of fetal ECG complex waveforms within the data (col 3, lines 43-45); (iii) determining differences in the shapes of a succession of fetal ECG complex waveforms over

Art Unit: 3762

time; and (iv) determining from the determined differences (col 3, lines 45-53) a number of fetal movements during the period of time (col 11, lines 50-61). Note that each disclosed QRS complexes of the fetal heart signals comprises of its own shape based on the variations of the QRS of the particular heart beat signals (col 3, ln 40-53).

In reference to **claim 23**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 22 in which step (i) comprises obtaining fetal ECG data from a plurality of electrodes positioned at different locations on the maternal abdomen (Figure 2, 301-303 & 304).

In reference to **claim 24**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 23 in which step (ii) includes the step of discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform (col 10, lines 5-50).

In reference to **claim 25**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 24 in which step (ii) includes subtracting the maternal ECG complexes from the received waveform (Figure 1, 204).

In reference to **claim 26**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 22 in which step (ii) comprises identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

Art Unit: 3762

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 7-11 & 27-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) in view of Marossero et al. (US 20050267376).

In reference to **claims 7 & 27**, Nagel et al. shows all the features of the instantly claimed invention as discussed above including a comparator [Nagel, Amplitude matching device-see e.g., (Figure 3b, 8)].

Nagel et al. fails to disclose ECG templates corresponding to different fetal presentations.

Marossero et al. teaches a variety of templates corresponding to different fetal presentations [0190] and comparing each of the identified fetal ECG waveforms with a set of predetermined ones of the fetal ECG complex templates [Marossero, 0183] and determining at least one template from said set of templates that best matches each identified fetal ECG waveform [Marossero, 183].

It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated a variety of templates corresponding to different fetal presentations in the apparatus of Nagel et al., in light of the teachings of Marossero, in order to provide predictable results pertaining to accurately providing fetal presentation by the highest correlation coefficient so as to best identify fetal ECG waveforms [Marossero, 183].

In reference to **claim 8**, Nagel et al. teaches in view of Marossero et al., the apparatus (Nagel, col 3, line 42) of claim 7 in which the memory (Figure 3b, 7) stores a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position relative to a specific electrode configuration [Marossero, 0183].

Art Unit: 3762

In reference to **claim 9**, Nagel et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 in which the event logger (Figure 3b, 7) records occasions on which the determined template changes (col 3, lines 53-61).

In reference to **claim 10**, Nagel et al. in view of Marossero et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 further includes means for selecting the set of predetermined fetal ECG templates according to a configuration of ECG electrodes positioned on the maternal abdomen [Marossero, 0183].

In reference to **claim 11**, Nagel et al. in view of Marossero et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 in which the set of predetermined fetal ECG templates (col 3, lines 39-40) includes templates corresponding to at least cephalic presentation (Marossero, Figure 12A), breech presentation (Figure 12B), shoulder dorsoanterior presentation and shoulder dorsoposterior presentation (Figure 12C).

In reference to **claim 28**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which step (iv) comprises determining the number of successive occasions on which the determined template changes during the period of time [Marossero, 0190].

In reference to **claim 29**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which the set of predetermined fetal ECG templates is selected according to a configuration of ECG electrodes positioned on the maternal abdomen [Marossero, 0183].

In reference to **claim 30**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which the set of predetermined fetal ECG templates

Art Unit: 3762

(col 3, lines 39-40) includes templates corresponding to at least cephalic presentation (Marossero, Figure 12A), breech presentation (Figure 12B), shoulder dorsoanterior presentation and shoulder dorsoposterior presentation (Figure 12C).

5. **Claims 12-14 & 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4, 211,237) in view of Beach et al. (US 5,088,498).

Nagel et al. shows all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to teach a means for detecting phase changes in respect to the fetal ECG complex waveforms.

Beach et al. teaches the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (col 4, lines 5-11)

It would have been obvious to one of ordinary skill in the art at the time of the invention, to have included a phase detector which determines the approximate phases for ultrasounds reflected at each of several different depth, in the apparatus of Nagel et al., as taught by Beach et al. in order to provide predictable results pertaining to a precise indication for the distance traveled by the reflective tissue (Beach, col 4, lines 10-11).

In reference to **claim 12**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 1 in which the waveform processor (Figure 3b, 33) comprises means for detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] between successive fetal ECG complex waveforms (Nagel, col 3, lines 40-45).

In reference to **claim 13**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 12 in which the waveform processor (Figure 3b, 33) comprises means for detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] of one or more

Art Unit: 3762

predetermined magnitudes between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

In reference to **claim 14**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 12 in which the event logger (Figure 3b, 7) records occasions on which a phase change occurs [Beach, (col 4, lines 5-11) & (Figure 3)].

In reference to **claim 32**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 in which step (iii) comprises detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] of one or more predetermined magnitudes between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

6. **Claims 15-21 & 34-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) in view of Oriol et al. (US 5,596,993).

Nagel et al. shows all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to teach a manner in which differences in fetal complex waveforms are detected by change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference. Nagel et al. also fails to teach means for providing a display, a fetal heart rate monitor, an alarm and an electronic interface associated with monitoring fetal behavior.

Oriol et al. teaches a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [(col 9, lines 60-67) & (Figure 5A)]. Oriol et al. also teaches a monitoring system, which incorporates a display, a fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board (Figure 14, 108, 102, & 116-120).

Art Unit: 3762

It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system, which incorporates a display, fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board, in the system of Nagel et al., as taught by Oriol et al., thereby detecting differences in the fetal complex waveforms by change in the positive and or negative energy of the fetal ECG complex waveform relative to a reference, in order to provide predictable results pertaining to showing the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate (Oriol, col 9, lines 40-42 & 63-67), and in order to provide output data, such as warnings and recommendation, to the clinician (Oriol, col 19, lines 39-40 & 54-56).

In reference to **claim 15**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 1 in which the waveform processor (Figure 3b, 33) is adapted to determine differences in fetal complex waveforms (col 3, lines 40-50) by detecting change in the positive and/or negative energy of a fetal ECG complex waveform relative to a reference (Oriol, Figure 5A).

In reference to **claim 16**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 15 in which the waveform processor (Figure 3b, 33) is adapted to determine differences in fetal complex waveforms (col 3, lines 40-50) by detecting changes in the relative quantities of positive and negative energy of a fetal ECG complex waveform relative to a baseline (Oriol, Figure 5A).

Art Unit: 3762

In reference to **claim 17**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 15 in which the reference comprises a previous or average fetal ECG complex waveform [Oriol, (col 6, lines 5-14) & (Figures 1-4)].

In reference to **claim 18**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including a display for displaying a count of the number of fetal movements detected [Oriol, (col 20, lines 22-32) & (Figure 14, 108)].

In reference to **claim 19**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 wherein the waveform processor (Figure 3b, 33) further includes a fetal heart rate monitor (Oriol, Figure 14, 102).

In reference to **claim 20**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including an alarm for indicating if the number of fetal movements during a period of time falls below a predetermined threshold further including an alarm for indicating if the number of fetal movements during a period of time falls below a predetermined threshold [Oriol, (col 19, lines 23-29) & (Figure 13, 86)].

In reference to **claim 21**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including a memory for storing fetal movement event data (Figure 3b, 7) and an electronic interface for downloading said event data to a remote device [Oriol, A/D, DSP, and neural network board-see (Figure 14, 116-120)]. The examiner is interpreting the A/D, DSP, and neural network boards as performing the same tasks as an electronic interface as taught by the instantly claimed invention.

In reference to **claim 34**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 in which the differences determined (col 3, lines 40-50) in step

Art Unit: 3762

(iii) comprises change in the positive and/or negative energy of a fetal ECG complex waveform relative to a reference (Oriol, Figure 5A).

In reference to **claim 35**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 34 in which the differences determined (col 3, lines 40-50) in step (iii) comprise changes in the relative quantities of positive and negative energy of a fetal ECG complex waveform relative to a baseline (Oriol, Figure 5A).

In reference to **claim 36**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 34 in which the reference comprises a previous or average fetal ECG complex waveform [Oriol, (col 6, lines 5-14) & (Figures 1-4)].

In reference to **claim 37**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of displaying or logging a cumulative count of the number of fetal movements within the period of time (Oriol, Figure 13 & 14, 108).

In reference to **claim 38**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of monitoring fetal heart rate (Oriol, Figure 14, 102).

In reference to **claim 39**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of indicating an alarm condition if the number of fetal movements during the period of time falls below a predetermined threshold [Oriol, (col 19, lines 23-29) & (Figure 13, 86)].

Claim

Art Unit: 3762

7. **Claims 31 & 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) as applied to claim 27 above, and further in view of Beach et al. (US 5,088,498).

Nagel et al. discusses all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to discuss a means for detecting phase changes in respect to the fetal ECG complex waveforms.

Beach et al. teaches the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (col 4, lines 5-8)

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Nagel et al with the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depth as taught by Beach et al. in order to provide predictable results pertaining to a means for detecting phase changes in respect to the fetal ECG complex waveforms.

In reference to **claim 31**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which step (iii) comprises detecting phase changes (Beach, Figure 3) between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

In reference to **claim 33**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 31 in which step (iv) comprises determining the number of successive occasions (col 11, lines 10-25) on which a phase change occurs during the period of time (Beach, Figure 3).

Response to Arguments

2. Applicant's arguments filed 4 June 2008 have been fully considered but they are not persuasive. Therefore, the original non-final rejection regarding claims 1-39, sent on 30 October 2007 is maintained. See the above action.

In regards to independent claim 1, the Applicant argues that Nagel does not teach “an event logger determining from the determined differences [in the shapes of fetal ECG complex waveforms] a number of fetal movements during a period of time” as required. The Examiner disagrees with the argument and further points out that the disclosed stored sample in a memory is equivalent to the claimed event logger, in which each disclosed stored sample is a collection of fetal heart signal segments according to a first criterion compared to a second criterion. A difference between the two criteria are found by determining the "degree of coincidence" between the two, which is equivalent to finding the difference between a number fetal movements, in which fetal heart signals are an indicator of fetal movements as instantly claimed (col 3, ln 40-53). Also, note that each disclosed QRS complexes of the fetal heart signals comprises of its own shape based on the variations of the QRS of the particular heart beat signals (col 3, ln 40-53).

The Applicant also argues that Nagel does not disclose “fetal movements”. The Examiner disagrees with the argument and further points out that the disclosure of the present invention states that fetal movements can be determined based on ECG complex “types,” in which the ECG complexes provide an indication of fetal movement [0061]. Nagel et al. discloses that myographic signals, i.e. signals derived from muscle movements, are functions of cardiac movements, in so much that the recorded fetomaternal ECGs are also analyzed in such a

Art Unit: 3762

manner so as to provide information pertaining to fetal movements as is instantly claimed (col 11, ln 51-61).

Arguments pertaining to claims 2-6, 12-14, 15-30 are directed to claim 1.

In regards to claims 7-11, the Applicant argues that there is no teaching, suggestion of motivation that Nagel et al. and Marossero et al. can be combined. The Examiner disagrees with the argument and further points out that Marossero et al. teaches a variety of templates corresponding to different fetal presentations [0190] and comparing each of the identified fetal ECG waveforms with a set of predetermined ones of the fetal ECG complex templates [Marossero, 0183] and determining at least one template from said set of templates that best matches each identified fetal ECG waveform [Marossero, 183]. It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated a variety of templates corresponding to different fetal presentations in the apparatus of Nagel et al., in light of the teachings of Marossero, in order to provide predictable results pertaining to accurately providing fetal presentation by the highest correlation coefficient so as to best identify fetal ECG waveforms [Marossero, 0183].

In regards to claims 34-39, the Applicant argues that the combination of Nagel et al. in view of Oriol et al. does not show or suggest the use of neither an isoelectric line, a reference derived from a previous or average ECG waveform, nor an alarm when a determined number of fetal movements per unit of time falls below a predetermined threshold. The Examiner disagrees with the above arguments and further points out that Oriol et al. teaches a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [(col 9, lines 60-67) & (Figure 5A)]. Oriol et al. also teaches a monitoring system,

Art Unit: 3762

which incorporates a display, a fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board (Figure 14, 108, 102, & 116-120). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system, which incorporates a display, fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board, in the system of Nagel et al., as taught by Oriol et al., thereby detecting differences in the fetal complex waveforms by change in the positive and or negative energy of the fetal ECG complex waveform relative to a reference, in order to show the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate (Oriol, col 9, lines 40-42 & 63-67), and in order to provide output data, such as warnings and recommendation, to the clinician (Oriol, col 19, lines 39-40 & 54-56). In addition, Oriol et al. also teaches the use of a text window in which conveys information such as recommendations and/or warnings pertaining to fetal well-being, which is equivalent to the alarm instantly claimed (col 19, ln 23-29).

Arguments pertaining to claims 40-54 are moot in view of the restriction requirement and election of claims 1-39.

3. Applicant's arguments, filed 4 June 2008, with respect to the objections of the specification, drawings and claims, in addition to the 35 U.S.C. § 112 rejections of the claims have been fully considered and are persuasive. Therefore, the above objections and 112 rejections of specification, drawings and claims have been withdrawn.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762